DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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July 24, 2015

Grafenberg Labs
% Bosmat Friedman
Regulatory Consultant
MJRAC
1208-12 Rockford Road
Toronto, Ontario M2R 3A2
Canada

Re: K142726
Trade/Device Name: O Glide Personal Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: June 23, 2015
Received: June 25, 2015

Dear Bosmat Friedman,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142726

Device Name
O Glide Personal Lubricant

Indications for Use *(Describe)*
O Glide Personal Lubricant is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is not compatible with condoms.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(K) SUMMARY

[as required by section 807.92(c)]

O Glide Personal Lubricant

510(k) Number K142726

1. SUBMITTER

Applicant's Name and Contact Information:

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New York NY 10017
Tel: 212-599-5555 Ext. 143
Fax: 212-599-5554

Contact Person:

Bosmat Friedman
Regulatory Affairs Consultant; MJ RAC
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bosmat@pushmed.com

Date Prepared:

September 15, 2014 (Revised July 23, 2015)

2. DEVICE NAME AND CLASSIFICATION

Trade Name:

O Glide Personal Lubricant

Common or Usual Name:

Personal Lubricant

Classification Name: Condom
Product Code: NUC
Regulation No: 21 CFR 884.5300
Class: II
Classification Panel: Obstetrics/Gynecology

3. PREDICATE DEVICES

Primary Predicate Device:

Aloe Cadabra Personal Lubricant - K124044

4. DEVICE DESCRIPTION

The O Glide Personal Lubricant is a non-sterile, oil-based personal lubricant designed to supplement the body's own natural lubrication fluids and to enhance the ease and comfort of intimate sexual activity.

The O Glide Personal Lubricant is specifically formulated with naturally occurring plant derived oils. The specifications for the subject lubricant include appearance, odor, viscosity, total microbial count (TAMC), total combined yeast and molds count, and absence of pathogenic organisms (Pseudomonas aeruginosa, Staphylococcus aureus, Candida albicans, Coliforms, and Clostridia). Osmolality, pH, and antimicrobial effectiveness are not applicable to the subject device because it is an oil-based lubricant.

The product is bottled in an LDPE white plastic tube with a white flip top cap. The tube is packaged in a carton for sale to consumers.

5. INDICATIONS FOR USE

O Glide Personal Lubricant is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is not compatible with condoms.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject and predicate device have the same intended use. The subject and predicate devices do not have the same technological characteristics because the subject device is oil-based and the predicate is aloe-based. The different technological characteristics of the subject device do not raise different types of safety and effectiveness questions, as formulation differences are commonly addressed in personal lubricant 510(k) submissions. Accepted scientific methods exist to assess the effects of the different technological characteristics, including biocompatibility, condom compatibility, and stability testing.

7. PERFORMANCE DATA

Below is a list of the tests that have been performed and successfully completed for the O Glide Personal Lubricant.

Biocompatibility:

Cytotoxicity Study Using the ISO Elution Method

The test article was evaluated for potential cytotoxic effects using an in vitro mammalian cell culture test. The test article extract showed no evidence of causing cell lysis or toxicity.

ISO Acute Systemic Toxicity Study in Mice

The test article was evaluated for acute systemic toxicity in mice. There was no mortality or evidence of systemic toxicity from the extracts injected into mice.

ISO Maximization Sensitization Study

The test article was evaluated for the potential to cause sensitization in a guinea pig maximization test. The test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig.

ISO Vaginal Irritation Study with Histopathology

The test article was evaluated for the potential to cause irritation to vaginal tissue in rabbits. The test article extracts were considered to be a non-irritant to vaginal tissue of the rabbit.

Shelf Life:

The subject device has one-year shelf life based on the results of an accelerated aging study conducted in the proposed packaging. The subject device met its specifications over the duration of the proposed shelf life.

Condom Compatibility:

The subject device is labeled not for use with condoms.

8. CONCLUSION

The O Glide Personal Lubricant is substantially equivalent to the predicate device.